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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,731	01/16/2004	Christopher J. Bond	11669.136USU1	6901

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EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,731	BOND, CHRISTOPHER J.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7,9-16,18-34,36-40,42,44-46,48-66,68-74,76-85,90-96,98-99,102-114* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-7,9-16,18-34,36-40,42,44-46,48-66,68-74,76-85,90-96,98,99 and 102-114.

DETAILED ACTION

Claims 1-7,9-16,18-34,36-40,42,44-46,48-66,68-74,76-85,90-96,98-99,102-114 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1,3-7,9-12,15-16,22-24, 29-34,36-37,38-40,42, 44-46, 48-54, 59-60, 62-66, 68, 69-74,76, 96, 99; 2,18-21, 61,90-91,98; 105-114 drawn to a polypeptide comprising a CDRH3 region, classifiable in class 424, subclass 130.1.

II. Claims 25-28, 55-58, 77-80,102-104, drawn to a vectors and expression host products, classifiable in class 435 subclass 320.1.

III. Claims 81-85, 92-95 drawn to a method of generating and designing a CDRH3 scaffold, classifiable in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed, have a different effect in that the vectors of invention II may be used to prepare antibiotic resistant bacteria, whereas the CDRH3 comprising proteins of

invention I may not be used in such a manner. Additionally, the proteins of invention I have a distinct three-dimensional structure, a design not shared by the vectors of invention II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides comprising a CDRH3 domain may prepared by random mutagenesis followed by screening.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product the vectors of invention II may be used to prepare antibiotic resistant bacteria, thus not exclusively for the generating and designing a CDRH3 scaffold comprising polypeptide, as set forth in invention III.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species Election

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Each genus identified below is indicated in **bold.** Applicant is requested to elect one species from within *each* genus of the elected invention, from which the search will commence.

Applicant is required to elect one **antibody structure** selected from the group consisting of: polypeptide comprising a *CDRH3 domain* (Claims 1,3-7,9-12,15-16,22-24, 29-34,36-37,38-40,42, 44-46, 50-54, 59-60, 62-66, 68, 69,76, 96, 99); *monobody* (claims 2,18-21, 48-49, 70-74, 61,90-91,98); and *CDHR3 scaffold* (claims 105-114) Currently, claims 1,3-7,9-12,15-16,22-24, 29-34,36-37,38-40,42, 44-46, 48-54, 59-60, 62-66, 68, 69-74,76, 96, 99; 2,18-21, 61,90-91,98; 105-114 are generic.

The species are independent or distinct because, they do not share a common structural core. Specifically, the CDRH3 polypeptide does not have a defined core, the monobody comprises an immunoglobulin beta sandwich and the CDHR3 scaffold consists of one immunoglobulin domain.

(From Claims 5-7,9-16, 31-34,36, 38-40, 46, 48-51, 59-66,69,96,99) Applicant is required to elect a single particular species of **CDRH3 polypeptide** including all structural amino acid residue(s) and position(s); all variant amino acid(s) and position(s); all non-structural amino acid residue(s) and position(s); all residues at framework 2 positions 37,45,91 and CDRH3 sequence (claims 59-66,69,96,99) for search purposes. Currently claims 1,5-7, 9-16, 31-34,36, 38-40, 46, 48-51 59-66,69,96,99 are generic.

(From Claims 18-21, 48-49, 70-74) Applicant is required to elect a single particular species of **monobody** including all structural amino acid residue(s) and

position(s); all non-structural amino acid residue(s) and position(s); all residues at framework 2 positions 37,45,91; CDRH3 sequence (claims 70-74, 90-91) all variant amino acid(s) and position(s) for search purposes. Currently claims 2, 18-21, 29,31-34,36, 38-40, 46 are generic.

(Claims 24,54) Applicant is required to elect a **viral coat protein** selected from the group set forth in claim 24. Currently claims 1,22-24 are generic.

The species are independent or distinct because, they do not share a common structural core.

(Claims 107-109) Applicant is required to elect a single particular **N terminal sequence** as set forth in claims 107-109. Currently claims 105, 107-109 are generic.

The species are independent or distinct because, they do not share a common structural core.

(Claims 110-111) Applicant is required to elect a single particular **C terminal sequence** as set forth in claims 110-111. Currently claims 105, 110,111 are generic.

The species are independent or distinct because, they do not share a common structural core.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

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MARK SHIBUYA, PH.D.
PATENT EXAMINER